Breast Cancer Biomarkers in Nipple Aspirate Fluid and Blood in Healthy Women

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24678

Source
NTR

Health condition

Breast cancer

Sponsors and support

Primary sponsor: Private sponsor and private foundation
Source(s) of monetary or material Support: Private donor and private foundation

Intervention

Outcome measures

Primary outcome

The main study parameters is the degree and patterns of microRNA expression in NAF and blood of healthy women, and to compare this with the pattern of women with breast cancer (ORNAMENT study, Trial NL6031)

Secondary outcome

Secondary parameters are optimization of RNA sequencing in NAF and the assessment of miRNAs in NAF derived exosomes. In addition, we assess discomfort, uncertainty and distress experienced by subjects undergoing NFA.

Study description

Background summary

Rationale: Breast cancer develops by the stepwise accumulation of interacting epigenetic and genetic events over time. While genetic events are specific processes that differ greatly between patients, epigenetic events are more generally occurring during breast cancer development. Therefore, epigenetic monitoring (in addition to genetic monitoring) could become a breakthrough in breast cancer prevention. Diagnostically there is a need for better procedures that can predict accurately who will and who will not develop breast cancer. Circulating miRNAs can be easily measured in body fluids such as nipple aspirate fluid (NAF) and blood, which could offer a promising minimally invasive method to complement current breast cancer screening methods. This study is part of a larger project that aims to assess the microRNA expression levels in NAF and blood of women with recently diagnosed breast cancer. Those expression levels will be compared to those obtained in this healthy control study. The results from this project will be further validated in a nested case-control study (NAF study). The ultimate goal is to develop a tool that enables a more accurate early prediction of the onset of breast cancer, to monitor development of microRNA expression patterns in NAF and blood of women at high risk for breast cancer.

Objective: The main goal of this study is to evaluate the normal expression levels of microRNAs in NAF and blood to determine baselines that will lead to cut-off values for the detection of breast cancer. The results will be compared with microRNA levels obtained just before primary surgery from patients with suspicion of, or histologically proven, breast cancer. We will perform stability analysis of candidate endogenous controls, and choose a microRNA that then can be used as endogenous control for real-time quantitation of miRNAs in NAF and blood in healthy subjects, women at high risk of developing breast cancer and breast cancer patients.

Study design: This study has a cross-sectional design and healthy women will be included. NAF and blood will be obtained once and the women will not be followed over time.

Study objective

The main goal of this study is to evaluate the normal expression levels of microRNAs in NAF and blood to determine baselines that will lead to cut-off values for the detection of breast cancer. The results will be compared with microRNA levels obtained just before primary surgery from patients with suspicion of, or histologically proven, breast cancer. We will perform stability analysis of candidate endogenous controls, and choose a microRNA that then can be used as endogenous control for real-time quantitation of miRNAs in NAF and

blood in healthy subjects, women at high risk of developing breast cancer and breast cancer patients.

Study design

Not applicable

Intervention

A onetime dose of 4 IE oxytocin nasal spray is administered prior to the nipple fluid aspiration (NFA) procedure. NAF is obtained through the use of a manual vacuum-system. In addition, three vials of blood will be taken

Contacts

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Eligibility criteria

Inclusion criteria

- Female
- Healthy
- Non-lactating
- Over the age of 45 years

Exclusion criteria

- Male
- Age under 45 years
- Bilateral ablative breast surgery

- Bilateral breast reduction with nipple graft
- Pregnancy or lactation
- Active breast infection
- Personal history of DCIS or invasive breast cancer
- > 20% risk of developing breast cancer

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2017
Enrollment:	187
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	16-10-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8987
Other	METC UMCU : METC 12-495

Study results

Summary results

Patuleia SIS, van Gils CH, Oneto Cao AM, Bakker MF, van Diest PJ, van der Wall E, Moelans CB. The Physiological MicroRNA Landscape in Nipple Aspirate Fluid: Differences and Similarities with Breast Tissue, Breast Milk, Plasma and Serum. Int J Mol Sci. 2020 Nov 11;21(22):8466. doi: 10.3390/ijms21228466. PMID: 33187146; PMCID: PMC7696615.